Teva Pharmaceuticals USA Inc.

CORRECTION – Note: Recall includes packages of 25

URGENT DRUG RECALL – USER LEVEL – INITIATED October 27, 2009

Propofol Injectable Emulsion, 10mg/ml (20ml Vial)

MANUFACTURED BY:
Teva Parenteral Medicines Inc.
Irvine, CA 92618

RECALLED BY:
Teva Pharmaceuticals USA Inc.
Sellersville, PA 18960

Lot #	Exp Date	NDC #	NDC #
31308134B	8/2011	0703-2856-01 – Individual Vials	0703-2856-04 – **Package of 25 Vials**
31308278B	8/2011	0703-2856-01 – Individual Vials	0703-2856-04 – **Package of 25 Vials**
31308279B	8/2011	0703-2856-01 – Individual Vials	0703-2856-04 – **Package of 25 Vials**
31308350B	9/2011	0703-2856-01 – Individual Vials	0703-2856-04 – **Package of 25 Vials**
31308659B	9/2011	0703-2856-01 – Individual Vials	0703-2856-04 – **Package of 25 Vials**
31308784B	9/2011	0703-2856-01 – Individual Vials	0703-2856-04 – **Package of 25 Vials**
31308785B	9/2011	0703-2856-01 – Individual Vials	0703-2856-04 – **Package of 25 Vials**
31309201B	9/2011	0703-2856-01 – Individual Vials	0703-2856-04 – **Package of 25 Vials**

Teva Parenteral Medicines, Inc. is voluntarily recalling eight (8) lots of Propofol Injectable Emulsion identified above. These lots were distributed between September 21, 2009 and October 19, 2009. No other lots are impacted by this recall.

Teva has initiated this voluntary recall because some of the containers may have been exposed to microbial contamination. The source of the contamination has been identified by Teva from equipment used in the manufacturing process. Teva has not received any reports of adverse events from its customers. This recall is being conducted as a precautionary measure. Teva has identified the root cause and corrective actions are being implemented.

Teva has notified the U.S. Food and Drug Administration (FDA). This recall has not yet been assigned a class by the FDA.

Wholesaler / Distributor / Retailer / User Level - Please perform the following activities:

- Please examine your inventory immediately for the specified lots of Propofol Injectable Emulsion, 10mg/mL. Our records indicate we shipped this product between September 21, 2009 and October 19, 2009.
- Immediately discontinue use and distribution of the product lots being recalled.
- Please perform a SUB-RECALL to ALL accounts.
- Promptly complete the attached recall stock response and reply via fax **215-799-5440** or mail, even if you have **no** product to return.

Upon receipt of your completed Recall Stock Response form, Teva Pharmaceuticals USA Inc. will fax or send a Return Goods Authorization form. Appropriate credit for recalled product returns, plus handling and shipping expenses, will be issued upon receipt of said product with the Return Goods Authorization at Teva Pharmaceuticals USA, Inc., 1090 Horsham Road (PO Box 1090), North Wales, PA 19454. Recalled product returned without a Return Goods Authorization form may delay the issuance of your credit.

This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is much appreciated. If you have questions or need additional information regarding this recall, please call **1-866-262-1243**. Please forward stock responses to Denise Plank, Regulatory Compliance via fax at 215-799-5440 or contact via phone at 215-799-5348.

Sincerely,

Sean M. Israel
Director, Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals USA Inc.

URGENT DRUG RECALL – USER LEVEL - INTIATED October 27, 2009

RECALL STOCK RESPONSE

PLEASE COMPLETE AND RETURN THIS RESPONSE
EVEN IF YOU HAVE NO RECALLED PRODUCT TO RETURN

_____
Customer Name

_____
Address

_____
City, State, Zip

Propofol Injectable Emulsion, 10mg/ml (20ml Vial)

RA REQUEST#: FIRST SECOND

NO STOCK: We have no stock of the recalled lot to return (Mark "**X**")_____

STOCK REMAINS: We have stock of this recalled product to return.

Lot #	Exp Date	# of SINGLE Vials NDC 0703-2856-01	# of Package of 25 Vials NDC 0703-2856-04
31308134B	**8/2011**		
31308278B	**8/2011**		
31308279B	**8/2011**		
31308350B	**9/2011**		
31308659B	**9/2011**		
31308784B	**9/2011**		
31308785B	**9/2011**		
31309201B	**9/2011**		

Name _____ Phone # _____
(Please Print)
Date _____ Fax # _____

Wholesaler: **If your location is different from above, please detail below**
Retailer / User Level: **Please provide your supplier name and location below.**

Distributor / Wholesaler Name:_____

Location (City & State):_____

Inquiries regarding this recall are to be directed to the following:

Stock Responses MUST first be received by: Denise Plank, FAX # 215 799-5440 to receive RA

Teva Returns, (RA) – Email - tevareturns@tevausa.com or (P)) 215-591-8859

Clare Davis, Medical Affairs, (Medical Related) – (P) 215-641-6974

Rachel Slifer, Accounts Receivable, (Credit) – (P) 215-591-8566